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Eltha D. Paskett 3-13-00  
PI - Signature Date

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## INTRODUCTION:

Soybeans and other legumes contain large amounts of plant estrogens known as isoflavones. Specific isoflavones found in soy (genistein and diadzein) have been implicated in reducing breast, colon, and prostate cancer risk in both laboratory-based studies (1). Strong evidence for an effect on prostate cancer risk comes from cross-cultural studies which have shown that prostate cancer rates are much lower in the Pacific Rim countries where soy products comprise a much higher proportion of the normal diet compared to the United States (2). This study proposes to conduct a randomized double-blind clinical trial which will assess the ability of a soy protein dietary supplement (a rich source of isoflavones) to reduce prostate cancer risk in older men. This project will randomize 120 men (60 white men and 60 African-American men) aged 55 years or older with high PSA levels but normal prostate biopsies into one of two groups (soy protein supplementation with isoflavones or casein protein supplementation). The specific aims of the study are: 1) to determine the impact of the interventions on the prostate, including changes in clinical (PSA levels and prostate volume) and intermediate (Ki-67, apoptosis, sex-steroid receptors, angiogenesis, antioxidant enzyme expression) markers of prostate cancer risk (3,4); 2) to assess soy protein effects on hormone levels, plasma lipids/lipoproteins and blood pressure; and 3) to evaluate changes in health-related quality of life, including urinary symptoms and sexual functioning. This project will involve the collaborative efforts of a multidisciplinary team affiliated with the cooperative group, Cancer and Leukemia Group B (CALGB), which has substantial expertise in the areas of controlled clinical trials, oncology, epidemiology, health-related quality of life, biostatistics, and nutrition. If positive results are obtained in this trial, soy supplementation may provide an important tool for the prevention of prostate cancer.

## BODY:

### ACCOMPLISHMENTS ASSOCIATED WITH THE APPROVED STATEMENT OF WORK

#### Task 1:

- a. The study forms and questionnaires have been developed and approved by the CALGB and NCI.
- b. The Soy and Casein shipments are being accepted from PTI by the study, in powder form, rather than the original juice box form.
- c. Staff training sessions have been held in conjunction with the annual meetings of the CALGB. All sites have not had the opportunity to attend; however staff have been identified and contacted at each of the remote sites. Training for the sites that did not attend the annual meetings will be done via phone.

#### Task 2:

- a. The recruitment phase had been on hold until the NCI approved the collaborative protocol with the CALGB. The four sites will begin recruitment shortly.
- b. Discussion and approval from the urology clinic physicians to begin the screening of their patients coming in for biopsies has been accomplished.

From this point, task 2 c, there is nothing to report for this annual reporting period. This is due to the delay in the approval of this CALGB protocol with the NCI.

### KEY RESEARCH ACCOMPLISHMENTS:

Sites have been identified; an NCI approved protocol and questionnaires have been developed; product has been received at the Wake Forest University School of Medicine; pathology and urology contacts at each site have been finalized. A study name, logo and brochure have been developed. We have also secured arrangements with MD Anderson to use a Food Frequency with added soy-containing foods for this study.

### REPORTABLE OUTCOMES:

None to report during this annual reporting period.

## CONCLUSIONS:

This annual reporting period, does not represent the usually progressive and timely working standards of the Wake Forest University School of Medicine. The efforts to collaborate with the NCI and CALGB in this study delayed the start of task 2 of the statement of work. During the next annual reporting period we will have recruited our sample and have 3 and 6 month data on a good part of our sample.

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APPENDICES:

None.